

ORBIT classifications (harm outcomes)

The ORBIT II classification system for missing or complete outcome reporting in harm outcomes

Classification	Description	Level of reporting	Risk of bias [*]
Explicit specific harm outcome: measured and compared across treatment groups			
P1	States outcome analysed but reported only that p-value>0.05.	Partial	High Risk
P2	States outcome analysed but reported only that p-value<0.05.	Partial	High Risk
P3	Insufficient reporting for meta-analysis or full tabulation.	Partial	Low Risk
Explicit specific harm outcome: measured but not compared across treatment groups			
Q	Clear that outcome was measured and clear outcome was not compared.	NA	No risk
Explicit specific harm outcome: measured, not clear whether compared or not across treatment groups			
R1	Clear that outcome was measured but no results reported.	None	High Risk
R2	Result reported globally across all groups.	None	High Risk
R3	Result reported from some groups only.	None	High Risk
Specific harm outcome not explicitly mentioned: clinical judgment says <u>likely</u> measured and likely compared across treatment groups			
S1	Only pooled adverse events reported (could include specific harm outcome).	None	High Risk
S2	No harms mentioned or reported.	None	High Risk

Specific harm outcome not explicitly mentioned: clinical judgment says likely measured but no events

T1	Specific harm not mentioned but all other specific harms fully reported.	None	Low Risk
T2	No description of specific harms.	None	Low Risk

Specific harm outcome not explicitly mentioned, clinical judgment says unlikely measured

U	No harms mentioned or reported.	None	Low Risk
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Explicit the specific harm outcome was not measured

V	Report clearly specifies that data on the specific harm of interest was not measured.	NA	No Risk
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*Bias would occur if specific harm had been measured, but data were presented or suppressed in a way that would mask the harm profile of particular interventions.